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CLERK U.S. DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON  
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UNITED STATES DISTRICT COURT FOR THE  
WESTERN DISTRICT OF WASHINGTON  
AT TACOMA

UNITED STATES OF AMERICA,

Plaintiff,

v.

RICHARD MARSCHALL

Defendant.

CR 17-5226 RBL

INFORMATION

The United States Attorney charges:

**A. INTRODUCTION**

At all times relevant to this Information:

1. Under the Food, Drug and Cosmetic Act (hereinafter "FDCA"), "interstate commerce" meant commerce between any State or Territory and any place outside thereof, and commerce within the District of Columbia or within any other Territory not organized with a legislative body. 21 U.S.C. § 321(b).

2. Under the FDCA, "label" meant a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" was defined as all labels and other printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m).

1        3.        Under the FDCA, "drugs" were defined as, among other things, articles  
2 intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in  
3 man or other animals; articles (other than food) intended to affect the structure or any  
4 function of the body of man or other animals; and articles intended for use as a  
5 component of any such articles. 21 U.S.C. § 321(g).

6        4.        A drug intended for use in man which, because of its toxicity, or other  
7 potentiality for harmful effect, or the method of its use, or the collateral measures  
8 necessary to its use, was not safe for use except under the supervision of a practitioner  
9 licensed by law to administer such drug, or a drug which was limited by an approved  
10 application under 21 U.S.C. § 355 to use under the professional supervision of a  
11 practitioner licensed by law to administer such drug, could only be dispensed by a  
12 practitioner licensed by law pursuant to a lawful prescription. 21 U.S.C. § 353(b)(1).  
13 These drugs were commonly known as "prescription drugs." Dispensing a prescription  
14 drug without a valid prescription by a licensed practitioner was deemed by statute to be  
15 an act which caused the drug to be misbranded while held for sale. 21 U.S.C. § 353(b)

16        5.        A drug was misbranded if, among other things, its labeling was false or  
17 misleading in any particular. 21 U.S.C. § 352(a).

18        6.        A drug was also misbranded if the labeling on the drug did not bear  
19 adequate directions for use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant  
20 directions under which a layman could use a drug safely and for the purposes for which it  
21 was intended without a doctor's supervision. 21 C.F.R. § 201.5.

22        7.        Directions under which a layperson could use a drug safely could not be  
23 written for a prescription drug because such drugs could, by definition, only be used  
24 safely (if at all) at the direction, and under the supervision, of a licensed practitioner.  
25 Approved prescription drugs dispensed pursuant to a valid prescription from a licensed  
26 practitioner were exempt from the requirement for adequate directions for use by a  
27 layperson. But prescription drugs dispensed without a valid prescription by a licensed  
28 provider were necessarily misbranded for lacking adequate directions for use.

1        8.        Under the FDCA, the doing or causing of the following acts, among others,  
2 was prohibited:

3                a.        The introduction or delivery for introduction into interstate  
4 commerce of any drug that was misbranded (21 U.S.C. § 331(a));

5                b.        The receipt in interstate commerce of any drug that was misbranded,  
6 and the delivery or proffered delivery thereof for pay or otherwise (21 U.S.C. § 331(c));  
7 and;

8                c.        The doing of any act with respect to a drug, if such act was done  
9 while the drug was held for sale (whether or not the first sale) after shipment in interstate  
10 commerce, which resulted in the drug being misbranded (21 U.S.C. § 331(k)).

11        9.        Human Chorionic Gonadotropin (HCG) was a hormone produced in  
12 women during pregnancy. HCG intended for therapeutic uses or to affect the structure or  
13 function of the human body was a drug under 21 U.S.C. § 321(g). Certain prescription  
14 drugs containing HCG were approved by the FDA for the treatment of infertility or other  
15 hormonal disorders. No HCG drug was approved by the FDA to treat obesity or promote  
16 weight loss. Any injectable HCG drug intended to treat obesity or promote weight loss  
17 was a prescription drug.

18                **B.        Richard Marschall's Prior Conviction**

19        10.        On or about September 26, 2011, RICHARD MARSCHALL was convicted  
20 of introducing a misbranded drug into interstate commerce with the intent to deceive,  
21 pursuant to Title 21, United States Code, Sections 331(a) and 333(a)(2). *See*  
22 *United States v. Richard Marschall*, CR11-5222BHS (W.D. Washington).

23        11.        RICHARD MARSCHALL's doctor of naturopathy license was suspended  
24 by the State of Washington Department of Health no later than November 20, 2013.  
25 RICHARD MARSCHALL did not possess an active medical license at any point  
26 thereafter.  
27 /  
28 /

1  
2 **COUNT 1**  
3 **(Introduction of Misbranded Drugs Into Interstate Commerce)**

4 12. Paragraphs 1-11 of this Information are incorporated by reference as if set  
5 forth fully herein.


6 13. On or about October 28, 2016, in Port Angeles, in the Western District of  
7 Washington, and elsewhere, RICHARD MARSCHALL, after having been convicted of a  
8 violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), did, with the  
9 intent to defraud and mislead, introduce, deliver, and cause the introduction and delivery  
10 for introduction into interstate commerce, from Port Angeles, Washington, to various  
11 locations outside of Washington State, of drugs, to wit: products containing injectable  
12 Human Chorionic Gonadotropin (HCG), which were misbranded as defined at Title 21,  
13 United States Code, Section 352(f)(1) in that the drugs lacked adequate directions for use  
14 and were not exempt from this requirement.

15 All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

16  
17 DATED this 20<sup>th</sup> day of June, 2017.

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20   
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